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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,538	03/11/2005	Chester Sutterlin	072US1	8929

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EXAMINER	
CUMBERLEDGE, JERRY L	
ART UNIT	PAPER NUMBER
3733	
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10/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/527,538	SUTTERLIN ET AL.	
	Examiner	Art Unit	
	JERRY CUMBERLEDGE	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *58,59,61-69 and 71-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *58,59,61-69 and 71-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 58, 59, 61-69 and 71-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koros et al. (US Pat. 5,795,291) in view of Allen (US Pat. 5,733,288) in view of Ouchi (US Pat. 5,899,850).

Koros et al. disclose a method comprising the steps of: creating a working channel from a patient's skin to an intervertebral disc space (Fig. 1); positioning a protector (Fig. 1, ref. 15) near an entrance into said intervertebral disc space and at least one of neural tissue, dura tissue, and vasculature adjacent to said entrance (Fig. 1), said protector having a longitudinal axis (Fig. 1) and including a retractor (Fig. 1) having at least two blade members (Fig. 1, ref. 14, 114) for establishing a barrier between said brush member and said body tissue adjacent to said entrance (Fig. 1), said blade members having a generally rectangular planar shape (Fig. 1)(Fig. 6, ref. 150, 205), said blade members positioned in a co-planar orientation relative to said longitudinal axis of said protector (Fig. 1). The step of creating a working channel to the intervertebral disc space is accomplished via at least one of percutaneous surgical procedure and an open surgical procedure (Fig. 1). The at least two blade members of said retractor includes a first blade member for retracting said neural tissue and a

second blade member for retracting said dura tissue (Fig. 1, e.g. ref). The first blade member and second blade member have a fixed angle therebetween (Fig. 1, when fixed in position). The first blade member and second blade member have a variable angle therebetween, since the positions can change because the device is adjustable (Fig. 1). The retractor includes a handle assembly for varying said angle between said first blade member and said second blade member (Fig. 25, ref. 44).

Koros et al. disclose the claimed invention except for inserting a brush member into the intervertebral disc space, said brush member having a length ranging from 0.25 to 4.0 inches, a diameter ranging from 0.082 to 1.225 inches, and a plurality of bristle members disposed in a helical configuration defining a capacity for carrying intervertebral disc material; manipulating said brush member within said intervertebral disc space to receive intervertebral disc material within said brush member; and removing said brush member from said intervertebral disc space. Koros et al. do, however, disclose that the retractor. Koros et al. do disclose that the retractor is used to hold open an incision during a spinal surgical procedure (abstract)(column 3, lines 35-67).

Allen discloses a method for removing intervertebral disc material, comprising the steps of: inserting a brush member into said intervertebral disc space (column 1, lines 55-63)(column 1, lines 10-15), since to remove the fibrous tissue, *e.g.* the spinal disc, the brush member must be placed within the disc space, where the disc resides, said brush member having a plurality of bristle members (Fig. 2, near ref. 10) defining a capacity for carrying intervertebral disc material (Fig. 10, since disc material can be

received within the spaces between the bristles)(column 3, lines 16-19); manipulating said brush member within said intervertebral disc space to receive intervertebral disc material within said brush member (column 5, lines 1-4); and removing said brush member from said intervertebral disc space (Fig. 2, since the device is clearly designed to be removed from the body when the surgery is completed). The brush member includes a stem member (Fig. 2, ref. 20), and further includes the step of providing a drive assembly (column 5, lines 1-6, i.e. the rotary hand piece) capable of engaging with said stem member for manipulating said brush member within said intervertebral disc space (column 5, lines 1-6). The drive assembly comprises one of a powered drive assembly coupled to said stem member and a manual drive assembly coupled to said stem member (column 5, lines 1-6, i.e. the rotary hand piece). The powered drive assembly is a power drill (column 2, lines 59-62). The manual drive assembly includes a handle member capable of being coupled to said stem member (Figs. 5-7, column 5, lines 1-6, i.e. the rotary hand piece must comprise a stationary portion to grip, or the device would spin from the surgeons hands when used). The drive assembly includes a stop member (Fig. 5, lip to the right of the brush member) coupled to said stem member for controlling the depth to which said brush member can be advanced into said intervertebral disc space. Allen discloses a device that is used in the spine (column 1, lines 55-63)(column 1, lines 10-15) that would require an incision to be made and held open in order to place the device along the spine (Fig. 5-7).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have utilized a device and steps of using a retractor as

taught by Koros et al. with the steps of using a brush as taught by Allen, since the device of Allen requires a incision to remain open as the surgical procedure is performed and the device of Koros et al. is disclosed as being used to hold open an incision in the spine.

Koros et al. in view of Allen discloses the claimed invention except for the bristle members being disposed in a helical configuration. Allen does, however, disclose bristles that are used to remove tissue (Allen, abstract).

Ouchi discloses a device (Fig. 1) with a brush (Fig. 1, ref. 2) that comprises bristles that are arranged in a helical pattern (Fig. 1, ref. 2A). The bristles are used for removing tissue (column 5, lines 50-60).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have substituted the bristles of Koros in view of Allen with helical bristles as taught by Ouchi, in order to achieve the predictable result of removing tissue. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the brush member with a length ranging from 0.25 to 4.0 inches and a diameter ranging from 0.082 to 1.225 inches, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Furthermore, Allen discloses the general condition that the brush can be used in methods involving spinal diseases (column 1, lines 10-26), which would require smaller brush sizes.

With regard to claims 60, 61, 68 and 69, Koros et al. in view of Allen discloses the claimed method except for the protector comprises a cannula dimensioned to extend to said entrance of said intervertebral disc space, said cannula having an inner lumen dimensioned to slideably receive said brush member for passage into said intervertebral disc space. The cannula includes a lip member at a distal end thereof dimensioned to retract at least one of said neural tissue, dura tissue, and vasculature adjacent to said spine. The inner lumen of said cannula and said brush member have approximately the same cross-sectional shape.

Ouchi discloses a method of inserting a brush member (Fig. 16, ref. 2) into tissue (column 1, lines 5-10), wherein prior to said step of inserting said brush member, positioning a protector (Fig. 16, ref. 6) which establishes a barrier between said brush member and other tissue, since the protector surrounds the brush (Fig. 16). The protector comprises a cannula (Fig. 16, ref. 6) dimensioned to extend to said entrance of said intervertebral disc space, said cannula having an inner lumen (Fig. 16, near ref. 14A) dimensioned to slideably receive said brush member for passage into said intervertebral disc space (Fig. 16 and Figs. 1, 2A, 2B). The cannula includes a lip member (Fig. 4, e.g. ref. 5) at a distal end thereof dimensioned to retract at least one of said neural tissue, dura tissue, and vasculature adjacent to said spine (Fig. 4), since as it expands it can retract tissue. The inner lumen of said cannula and said brush member have approximately the same cross-sectional shape (Fig. 16). This tube is useful in allowing the brush to be used for cytology purposes and prevents the cells collected from being knocked off of the brush (column 1, lines 10-30).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have created the method of Koros in view of Allen with the steps of using a protector as taught by Ouchi in order to allow the brush of Koros in view of Allen to be used for cytology and puposes and prevent the cells collected from being knocked off of the brush (column 1, lines 10-30).

Response to Arguments

Applicant's arguments with respect to claims 58, 59, 61-69 and 71-74 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY CUMBERLEDGE whose telephone number is (571)272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. C./
Examiner, Art Unit 3733
/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733